Date of Approval: February 16, 2021

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-506

Animec™ Plus

(ivermectin and clorsulon)

Injectable solution

Cattle

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

Sponsored by:

Chanelle Pharmaceuticals Manufacturing Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-506

B. Sponsor

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea, County Galway
Ireland

Drug Labeler Code: 061651

U.S. Agent Name and Address:
James H. Schafer, DVM
Schafer Veterinary Consultants, LLC
800 Helena Court
Fort Collins, CO 80524

C. Proprietary Name

Animec™ Plus

D. Drug Product Established Name

ivermectin and clorsulon

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

10 mg (1%) ivermectin and 100 mg (10%) clorsulon per mL

H. How Supplied

250 mL, 500 mL, and 1000 mL bottles

I. Dispensing Status

Over-the-counter (OTC)

J. Dosage Regimen

1 mL for each 110 lbs (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon.

K. Route of Administration

Subcutaneous

L. Species/Class

Cattle

M. Indications

Animec™ Plus is indicated for the effective treatment and control of the following parasites in cattle:

Gastrointestinal Roundworms (adults and fourth-stage larve):
Ostertagia ostertagi (including inhibited *O. ostertagi*)
O. lyrata
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata
C. pectinata
Bunostomum phlebotomum
Nematodirus helvetianus (adults only)
N. spathiger (adults only)
Oesophagostomum radiatum
Lungworms (adults and fourth-stage larvae):
Dictyocaulus viviparous
Liver Flukes:
Fasciola hepatica (adults only)
Cattle Grubs (parasitic stages):
Hypoderma bovis
H. lineatum
Sucking Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Manage Mites (Cattle Scab):
Psoroptes ovis (syn. *P. communis* var. *bovis*)
Sarcoptes scabiei var. *bovis*

Persistent Activity
Ivermectin and clorsulon injection has been proven to effectively control infections and to protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostronglyus axei* and *Cooperia punctata* for 21 days after treatment; *Haemonchus placei* and *Cooperia oncophora* for 14 days after treatment.

N. Reference Listed New Animal Drug (RLNAD)

ivomec® Plus; ivermectin and clorsulon; NADA 140-833; Boehringer Ingelheim Animal Health USA, Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Chanelle Pharmaceuticals Manufacturing Ltd., was granted a biowaiver for the generic product Animec™ Plus (ivermectin and clorsulon) Injection for Cattle. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is ivomec® Plus (ivermectin and clorsulon) Injection for Cattle, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 140-833, and was approved for use in cattle on September 17, 1990.

III. HUMAN FOOD SAFETY

The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of ivermectin is 5 micrograms *per* kilogram of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 1.6 parts *per* million is established for 22,23-dihydroavermectin B_{1a} (the marker residue) in liver (the target tissue), and 650 parts *per* billion in muscle, under 21 CFR 556.344.

The ADI for total residues of clorsulon is 8 micrograms *per* kilogram of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 1.0 part *per* million is established for clorsulon (the marker residue) in kidney (the target tissue), and 0.1 parts *per* million in muscle, under 21 CFR 556.163.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 21 days has been established for ivermectin and clorsulon in cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of ivermectin and clorsulon are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Animec™ Plus:

WARNING: NOT FOR USE IN HUMANS.
Keep this and all drugs out of reach of children.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects, obtain an SDS or for assistance, contact Chanelle Pharmaceuticals Manufacturing Ltd. at 001-353-91-841788.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that Animec™ Plus , when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from cattle treated with Animec™ Plus will not represent a public health concern when the product is used according to the label.